



# A COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFECTIVENESS OF *TAMBULA PATHRA SAINDHAVA LEPA* AGAINST *SIGRUPUNARNAVADI LEPA* IN *VRSCHIKA DAMSA*

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## ABSTRACT

Scorpion envenomation is a life-threatening toxicological emergency and considered as a major public health problem. It is prevalent in certain tropical and subtropical regions of the world. Scorpions are usually found in burrows of rats and other burrowing animals, under the bricks, stones and pile of garbage; here it rests for the entire day and venture out only after sunset to attack other creatures. Here the effect of *Tambulapathra saindhava lepa* against *Sigrupunarnavadi lepa* is evaluated in pain, erythema, burning sensation, and oedema at the site of sting. The study *Tambulapathra daindhava lepa* is mentioned for *Vrschika visha* in *Kriya kumudi*.

**Key words :** *Tambulapathra saindhava lepa*, *Vrschika visha*, *Sigrupunarnavadi lepa*, scorpions

## INTRODUCTION

*Vrschika* (scorpion) , a highly venomous living being , is usually found in burrows of rats and other burrowing animals, under the bricks, stones and pile of garbage ; here it rests for the entire day and venture out only after sunset to attack other creatures. It attacks human beings out of fear of being stampeded or run over<sup>[1]</sup>. There are more than 1250 species of scorpions. About 100 species are found in India. Scorpion venom is a clear, colourless toxalbumen and can be classified as either haemolytic or neurotoxic. It's toxicity is more than that of snakes, but only a small quantity is injected<sup>[2]</sup>. Of the nearly 100 species, the commonest are *Mesobuthus tumulus*(red scorpion) and *Palamneus swammerdami*(black scorpion). The former is more venomous<sup>[3]</sup>.

*Vrschika visha* has been described in detail under *keeta visa* . On the basis of their toxicity, scorpions are classified in to *manda visha vrschika*, *madhyama visha vrschika*, *mahavisa vrschika*.<sup>[4]</sup> *Visa*(sting/poison) of *Vrschika* (scorpion) is extremely *tiksna* (sharp); initially it causes *vahnivat daha* (burning sensation like a fire) and does a quick *urdhva rohana* ( upward movement) and latter settles at the site of *damsa* (bite) resulting in *atiruk* (excruciating pain) , *syava* (bluish discolouration) , *toda* (pricking pain) and *sphutana* (bursting pain)<sup>[5]</sup> .

## BACKGROUND AND RATIONALE OF STUDY

Scorpion envenomation is a life threatening toxicological emergency and considered as a major public health problem. It is prevalent in certain tropical and subtropical regions of the world . Scorpion envenomation is especially fatal in the first hours, usually due to respiratory and cardio vascular collapse. More than a million scorpion stings are reported through out the world annually, with an estimated prevalence of 20 per 100000 inhabitants . Approximately 5% of the reported cases are severe and only 0.3% of the severe cases are fatal. Scorpion envenomation may affect all individuals, but it is more prevalent in young people. 60% to 80% of them are older than 15 years, but it is more severe in children principally due to minor corporal surface. Domestic accidents in rural areas are considered the most common cause with 80 % of all recorded cases.<sup>[6]</sup>

Commonly used drugs in *Vrschika visa* are *Dasanga agada* <sup>[7]</sup>for internal use and *Sigrupunarnavadi lepa*<sup>[8]</sup> for external application. As the number of ingredients in *Sigrupunarnavadi lepa* is more and some of them are expensive there is a need for another simpler formulation. In *Kriyakoumudi* a *lepa* method is mentioned which is not explored much in present clinical practice. *Lepa* using *Tambula pathra*, *Saindhava lavana* would prove to be effective in relieving the symptoms of *Vrschika damsa* especially in pain management. Hence this study is an attempt to find out the effectiveness of *Tambula pathra saindhava lepa*<sup>[9]</sup> in *Vrschika damsa* along with internal administration of *Dasanga agada* .

## AIMS AND OBJECTIVES

### AIM

- To provide an effective and easily available lepa preparation in *Vrschika damsa*.

### OBJECTIVE

- To evaluate the effectiveness of *Tambula pathra saindhava lepa* along with *Dasanga agada* in *Vrschika damsa*.
- To evaluate the effectiveness of *Sigrupunarnavadi lepa* along with *Dasanga agada* in *Vrschika damsa*.
- To Compare the effectiveness of *Tambula pathra saindhava lepa* against *Sigrupunarnavadi lepa* along with *dasanga agada* in *Vrschika damsa*.

Table no : 1 Materials and methods

MATERIALS	METHODS
Availiable literature	Will be arranged systematically.
Drugs	<i>Dasanga agada</i> (both groups) <i>Tambula pathra saindhava lepa</i> (Trial group) <i>Sigrupunarnavadi lepa</i> (Control group)
Case Record Format	Will be prepared and data entry will be made.
Consent For	Will be prepared.
Research Participants	Will be recruited per plan through randomization.
Area of Study	Clinical

**STUDY DESIGN**

Comparative Clinical Trial.

**STUDY SETTINGS:**

Pappinissery Visha Chikitsa Kendra , Post graduate department of Agadatantra, MVR Ayurveda Medical college, Parassinikadavu, kannur.

**STUDY POPULATION:**

2 groups each of 20 Patients from Pappinissery Visha Chikitsa kendra ,Parassinikadavu, kannur with inclusion criteria will be selected.

**SELECTION CRITERIA****DIAGNOSTIC CRITERIA**

- History of acute scorpion sting.
- Pain at the site of sting.
- Burning sensation at the site of sting.
- Oedema at the site of sting.
- Erythema at the site of sting.

**INCLUSION CRITERIA**

- Diagnosed cases of scorpion sting within 48 hours.
- Age group between 16 to 60 years.
- Participants with symptoms like pain, burning sensation, oedema and erythema.
- Participants irrespective of gender, caste, religion, economic status

**EXCLUSION CRITERIA**

- Participants who have already undergone any other treatment for this condition.
- Participants with altered consciousness.
- Participants with systemic diseases.
- Pregnant women and lactating mother .
- Participants presenting with complications of sting like anaphylactic reactions.

**SAMPLE SIZE CALCULATION**

2 groups each of 20 participants

$$n = \frac{2SD^2(P+C/2)^2}{d^2}$$

where , P (Power) = 2.5

$$C \text{ (Confidence interval)} = 1.96$$

$$d \text{ (Mean difference)} = 1.2$$

$$SD \text{ (Standard deviation)} = 1.18$$

$$n = 39.86$$

## SAMPLING PROCEDURE

Simple random lottery sampling method.

Group 1- Trial group – 20 cases

Group 2- Standard group – 20 cases

## INTERVENTION

### DRUG SOURCE

- The ingredients of *Dasanga agada*, *Tambula pathra*, *saindhava lavana*, *Sigrupunarnavadi lepa choorna* purchased from the local market, identified and authenticated from Dravya guna Department of MVR Ayurveda Medical college, Parassinikadavu, kannur .
- Preperation - carried out from MVR Ayurveda Medical college Pharmacy as per GMP guidelines.

### PREPERATION OF MEDICINE:

Table no: 2 *Dasanga agada* <sup>[7]</sup>

INGREDIENTS	BOTANICAL NAME	FAMILY	MALAYAL AM NAME	PART USED	PROPORTION USED
VACHA	<i>Acorus calamus</i>	Araceae	vayambu	Rhizome	Equal parts
HINGU	<i>Ferula narthex</i>	Umbelliferae	kayam	Resin	Equal parts
VIDANGA	<i>Embelia ribes</i>	Myrsinaceae	Vizhal ari	Fruit	Equal parts
SAINDHAVAM	Rock salt		Induppu	Salt	Equal parts
GAJAPIPPALI	<i>Piper chaba</i>	Piperaceae	Athi thippali	Fruit	Equal parts
PATHA	<i>Cyclea peltata</i>	Menispermaceae	Pada kizhangu	Root	Equal parts
PRATHIVISHA	<i>Aconitum heterophyllum</i>	Ranunculaceae	Atividayam	Tuberous root	Equal parts
SHUNTI	<i>Zingiber officinale</i>	Zingiberaceae	chukku	Rhizome	Equal parts
MARICHA	<i>Piper nigrum</i>	Piperaceae	kurumulaku	Fruit	Equal parts
PIPPALI	<i>Piper longum</i>	Piperaceae	Thippali	Fruit	Equal parts

All the above drugs are taken in equal quantity by weight and made into handmade pills of 2 gm each according to *vati kalpana vidhi*.

Table no: 3 *Sigrupunarnavadi lepa choorna*<sup>[8]</sup>

DRUG	BOTANICAL NAME	FAMILY	MALAYALAM NAME	PART USED	PROPORTION
<i>Sigru</i>	<i>Moringa olifera</i>	Moringaceae	<i>Muringa</i>	Bark	Equal parts
<i>Punarnava</i>	<i>Boerhavia diffusa</i>	Nyctaginaceae	<i>Thazhuthama</i>	Root	Equal parts
<i>Haridra</i>	<i>Curcuma longa</i>	Zingiberaceae	<i>Manjal</i>	Rhizome	Equal parts
<i>Vacha</i>	<i>Acorus calamus</i>	Araceae	<i>Vayambu</i>	Rhizome	Equal parts
<i>Raktachandana</i>	<i>Pterocarpus santalinus</i>	Fabaceae	<i>Rakta chandanam</i>	Heart wood	Equal parts
<i>Pata</i>	<i>Cyclea peltate</i>	Menispermaceae	<i>Patha kizhangu</i>	Root	Equal parts
<i>Iswari</i>	<i>Aristolochia indica</i>	Aristolochiaceae	<i>Karalekam</i>	Root	Equal parts
<i>Yashtimadhu</i>	<i>Glycyrrhiza glabra</i>	Fabaceae	<i>Iratti madhuram</i>	Stem	Equal parts
<i>Shireesha</i>	<i>Albizia lebbek</i>	Fabaceae	<i>Nenmeni vaka</i>	Bark	Equal parts
<i>Gokshura</i>	<i>Tribulus terrestris</i>	Zygophyllaceae	<i>Njerinjil</i>	Seed	Equal parts

All the above drugs are taken in equal quantity by weight, dried and made in to sukshma choorna and lepa is prepared by adding sufficient quantity of water at the time of application.

Table no: 4 *Tambula pathra saindhava lepa*<sup>[9]</sup>

DRUG	BOTANICAL NAME	FAMILY	PART USED	MALAYALAM NAME
<i>TAMBULA</i>	<i>Piper betle</i>	Piperaceae	Leaf	<i>Vettilakodi</i>
<i>SAINDHAVA LAVANA</i>	Rock salt		salt	<i>Induppu</i>

- Tambula pathra and Saindhava lavana are taken in equal quantity.
- Tambula pathra is grinded in khalwayanthra and mixed with Saindhava lavana and grinded well and lepa is prepared as per the need at the time of application.

### WITHDRAWAL CRITERIA AND STOPPAGE RULES

- Patient if not co-operative to the procedure
- If symptoms get worsens
- Patient if experiences any complications
- Patients will be diagnosed according to the conditions and necessary management will be given.

### OUTCOME MEASUREMENT

The following subjective and objective variables will be assessed using different grading methods before and after treatment.

#### Subjective variables

- Burning sensation
- Pain

#### Objective variables

- Oedema
- Erythema

### PLAN OF ANALYSIS

The four main cardinal symptoms – pain, burning sensation, oedema, erythema are analysed. The changes in the above said parameters are noted at specific intervals and assessment were done accordingly. The overall relief obtained are assessed based on the results of the statistical analysis.

100% relief – cured

76% -99% relief - marked improvement

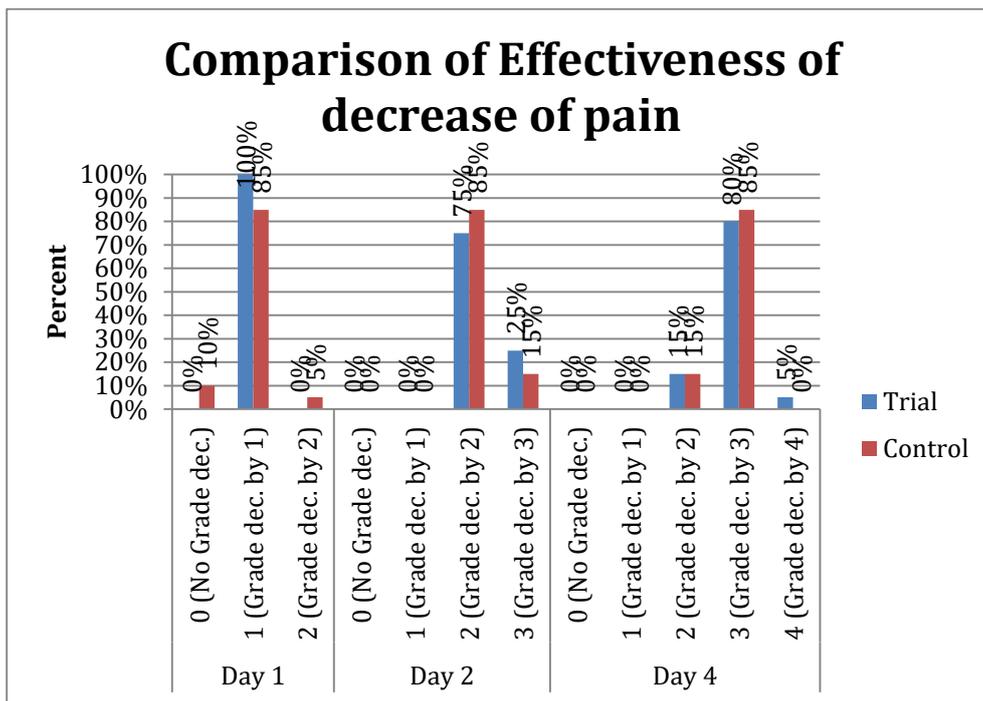
51% -75% relief – moderate improvement

26% - 50% relief - mild improvement

0-25% relief – unchanged

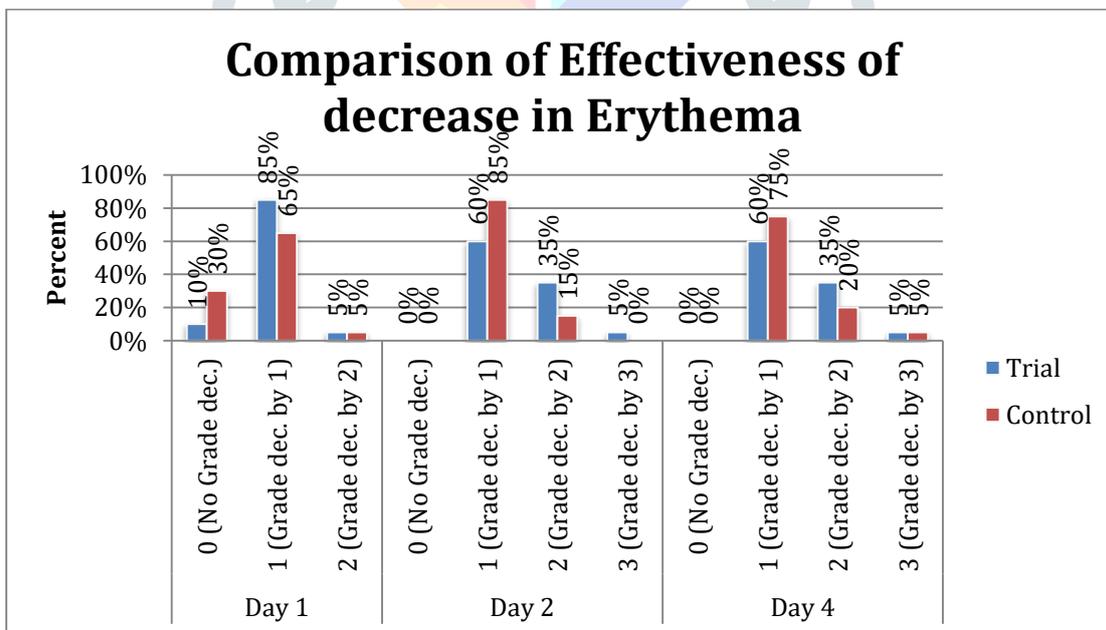
**RESULTS:**

**Fig 1: comparison of effectiveness of decrease of pain**



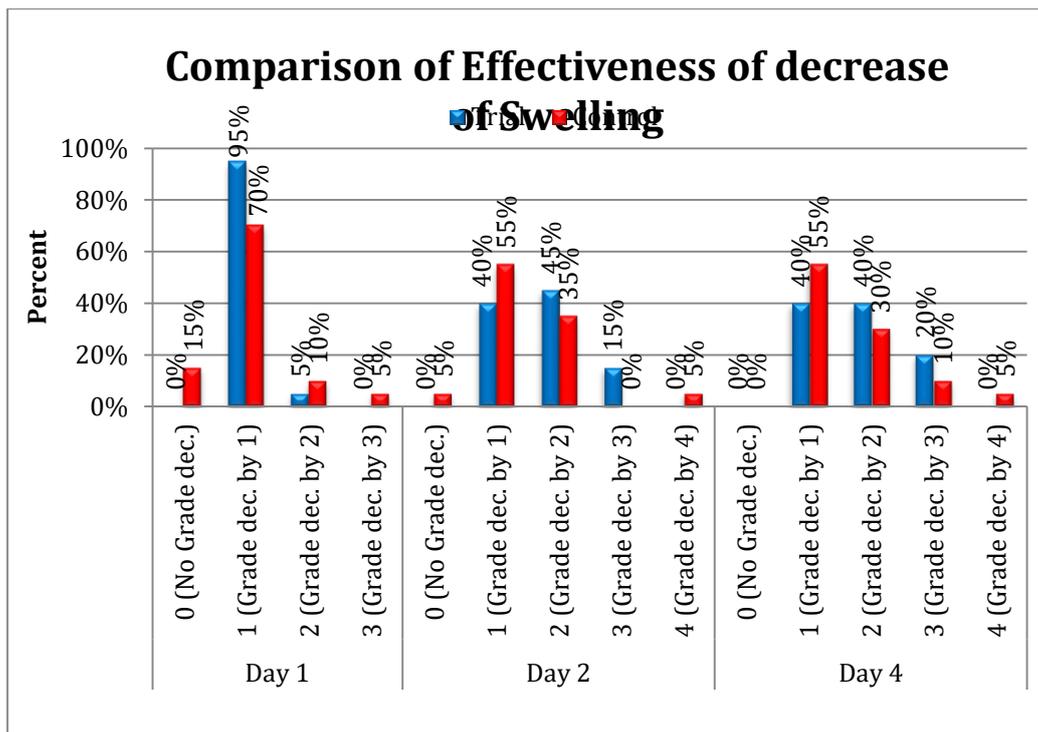
Here Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of pain between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

**Fig 2: Comparison of Effectiveness of decrease in Erythema**



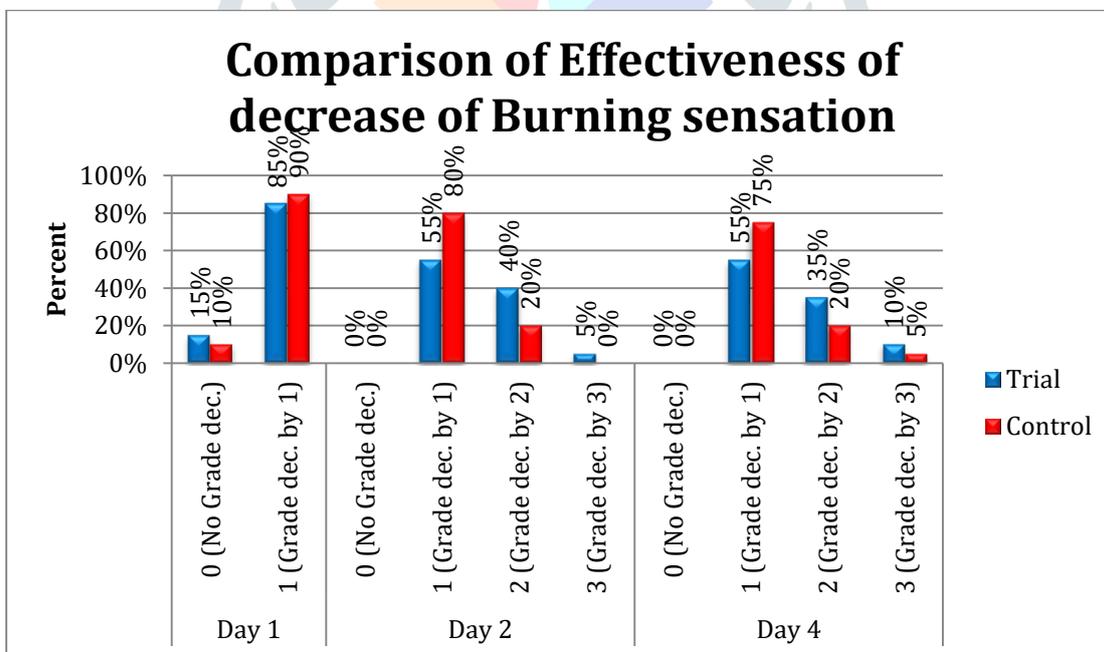
Here Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of Erythema between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

Fig 3: Comparison of Effectiveness of decrease of Swelling



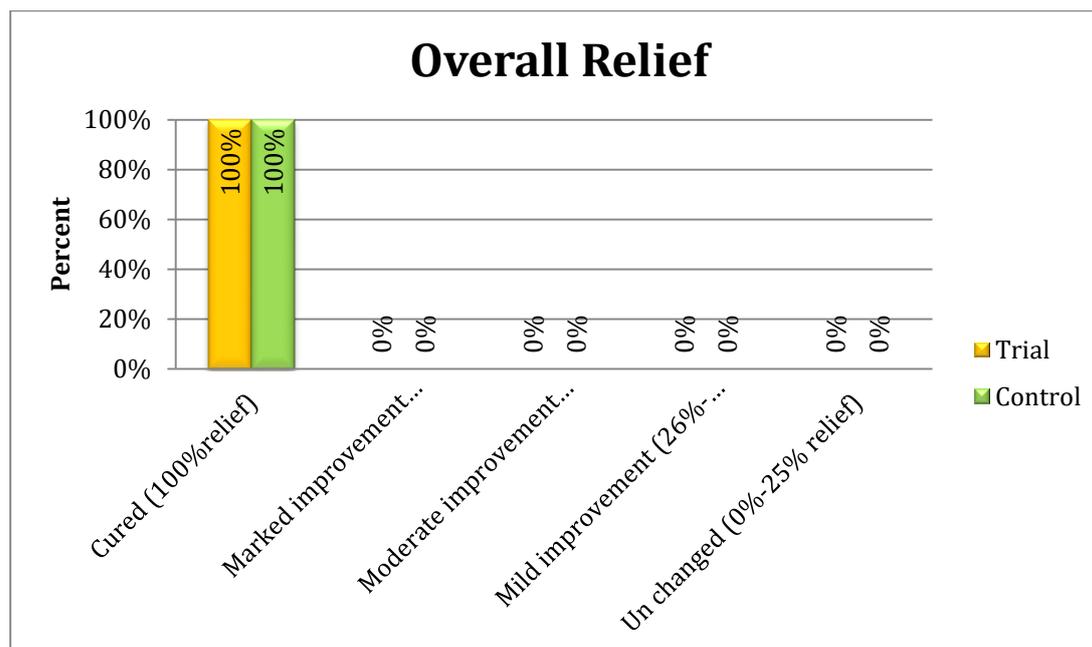
Here Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of Swelling between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

Fig 4: Comparison of Effectiveness of decrease of Burning sensation



Here Mann-Whitney U Test is used for the Comparison of Effectiveness of decrease of Burning sensation between Trial and Control group. There is no significant difference in Day 1, Day 2, Day 4, since the corresponding p value > 0.05.

Fig 5: Overall effect of therapy



There is no significant difference in overall relief between group 1 and group 2. Thus, statistically it is derived that *Tambula pathra saindava lepa* is equally effective when compared with *Sigrupunarnavadi lepa* in the management of pain, erythema, swelling and burning sensation caused by Scorpion sting.

## DISCUSSION

In *Dasanga agada*, almost all drugs have *vedanahara* and *sophahara* properties. Some of these drugs have *dahaprasamana*, *vishaghna*, *raktasodhaka* and *srotosodhaka* properties. 80% of drugs in *Sigrupunarnavadi* are of *ushna veerya*, and its action is mainly due to the *Vishahara* property. *Tambula* is *vatha kapha samaka*, *sophahara*, *vedanasthapana* helps in reducing the pain, and oedema produced by *Vrschika damsas*. *Saindhava lavana* possess *madhura rasa*, *laghu*, *snigdha*, *sookshma guna*, *seetha veerya*, *tridosahara*, *avidahi* properties. Hence a combination of these two drugs in the *yoga* when applied externally can reduce the main symptoms like pain, oedema, erythema and burning sensation.

## CONCLUSION:

The research design developed such that all the participants satisfying the inclusion and exclusion criteria was recruited into the study by simple random sampling. The participant of group 1 received *Tambula pathra saindava lepa* and group 2 received

*Sigrupunarnavadi lepa* for 2 days. In both the groups internally *Dasanga agada* was given for two days (thrice daily). Thorough clinical assessment was done in both the groups. The four cardinal symptoms (pain, oedema, burning sensation, erythema) were observed in study patients. Proper grading was done on various symptoms. The data was converted into tables and diagrams for analysis. Mann- whitney U test and Wilcoxon Signed rank test were used to draw the conclusion after analysis. All the parameters pain, erythema, oedema and burning sensation were equally effective in both the groups. Hence the null hypothesis can be rejected, accepting the

alternate hypothesis. Thus, statistically it is derived that *Tambula pathra saindava lepa* is equally effective when compared with *Sigrupunarnavadi lepa* in the management of *Vrschika damsas*.

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